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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/351,778	07/12/1999	WILLIAM S. M. WOLD	16153-7775	1203

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EXAMINER

ART UNIT PAPER NUMBER

DATE MAILED: 11/02/2006

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 09/351,778  
Filing Date: July 12, 1999  
Appellant(s): WOLD ET AL.

**MAILED**  
**NOV 02 2006**  
**GROUP 1600**

David L. Parker & Monica A. De La Paz  
For Appellant

**SUPPLEMENTAL EXAMINER'S ANSWER**

This is in response to the remand from the Board of Appeals filed 28 September 2006 in their decision on Appellant's Request for Rehearing filed 28 March 2006.

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*Response to Remand by the Board of Appeals.*

The Board of Appeals has remanded the application to the Examiner in order to consider whether there is potential interference under 37 CFR 41.203 between the instant application and either or both of Henderson et al., U.S. 6,197, 293, and Little et al., US 6,254,862, and consequently, whether the declaration under 35 USC 1.131 may be used as evidence for the purpose of overturning a rejection under 35 USC 102(e).

The Examiner has met with SPE Andrew Wang, an interference specialist in Tech Center 1600, and it was determined that there is no potential interference between the instant application and either of the two patents. Appellant has provided a two-way analysis between the instant application and each of the Henderson and Little patents at pages 8-14 of their Request for Rehearing filed 28 March 2006, which is incorporated herein by reference. Appellant argues based on their analysis that the instant claims and those of the Henderson and Little patents neither anticipate one another or render the other obvious when each is assumed to be prior art over the other.

The Examiner agrees with most of Appellant's analysis and conclusions, except that Appellant does not appear to have considered the description of the respective claimed inventions in the specifications of each of the patents, and is mistaken in suggesting that the claims of both Henderson and Little fail to anticipate or render obvious the instant claims.

The inventions of Henderson, Little, and Appellant have two basic elements defining the adenoviral vectors of their respective inventions. The first element relates to the type of adenoviral vector being claimed, and the second relates to the presence and level of expression of the adenoviral death protein, ADP. Appealed claims 13 and 60 require that the adenoviral vector

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be replication competent in neoplastic cells. This limitation is generic to that of the vectors of Henderson, which requires that the expression of an adenoviral gene required for replication of the adenovirus be under control of a probasin transcriptional regulatory element (TRE), and Little, which requires that the adenoviral E1A and E1B regions, which are essential for normal adenoviral replication, be under control of an  $\alpha$ -fetoprotein TRE. The vectors of both Henderson and Little replicate in certain types of neoplastic cells, and thus anticipate this element of the appealed claims.

With respect to the ADP gene, the claims of both Henderson and Little are generic to the appealed claims, which either require that ADP be overexpressed, e.g. appealed claim 13, or require modifications to the structure of the vector that would result in overexpression of ADP, e.g. appealed claim 60. None of the claims of either Henderson or Little require that ADP be overexpressed or that the adenoviral vector have any of the modifications relating to expression of ADP required by appealed claim 60. However, as held by the Examiner and affirmed by the Board, the description of the invention of both Henderson and Little teaches embodiments that would inherently result in overexpression of ADP or that meet some of the structural requirements set forth in appealed claim 60. Consequently, the claims of Henderson and Little, when read in light of their supporting description, would anticipate or render obvious the appealed claims.

While the claims of Henderson or Little, when read in light of their supporting description, anticipate or render obvious the appealed claims, the appealed claims do not anticipate or render obvious the claimed invention of either Henderson or Little. The appealed claims do not require that the replication of the adenovirus in neoplastic cells be under control of

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either a probasin TRE or an  $\alpha$ -fetoprotein TRE, nor does the instant specification mention, much less teach, an adenovirus with genes required for replication, e.g. E1A or E1B, being under control of a probasin TRE or an  $\alpha$ -fetoprotein TRE. Thus, the appealed claims would not anticipate the claims of Henderson or Little, either alone or when read in light of the instant specification. Furthermore, there is no art of record, nor is the Examiner aware of any such art, prior to the effective filing date of either Henderson or Little that when combined with the appealed claims would render the claims of either Henderson or Little obvious. Appellant has drawn the same conclusion in the Request for Rehearing, paragraph bridging pages 13-14.

Since the appealed claims, if assumed to be prior art, would neither anticipate nor render obvious the claims of Henderson or Little, there is no basis for a potential interference between the instant application and either of the Henderson or Little patents, and the two Wold declarations of 03 January ("Wold I") and 03 September 2006 ("Wold II") should not be deemed ineffective for being filed under 37 CFR 1.131.

*Supplemental arguments in response to section VII.C.1.c.(2)-(4) of the brief.*

The following additional comments in response to section VII.C.1.c.(2)-(4) of the brief are prompted by *Invitrogen Corp. v. Clontech Laboratories Inc.*, 77 USPQ2d 1161, recently decided by the Federal Circuit on 18 November 2005, and expand upon the Examiner's response to these arguments in pages 26-31 of the Examiner's Answer filed 29 December 2004. The *Invitrogen* decision is deemed by the Examiner to be relevant to the sufficiency or insufficiency of the evidence presented in the two Wold declarations under 37 CFR 1.131, filed 03 January

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("Wold I") and 03 September 2006 ("Wold II"). This decision was rendered and published well after the Examiner's Answer was filed.

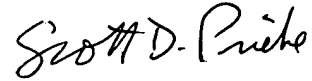
The court in *Invitrogen* held that the date of conception of an invention is the date on which the inventor first appreciated what he or she had made, and not necessarily the date on which something readable on the invention, a product in this case, was first made. The invention in question was a genetically engineered reverse transcriptase having DNA polymerase activity but lacking RNase H activity. It was established that Dr. Goff had made a mutant reverse transcriptase having DNA polymerase activity but lacking RNase H activity prior to the effective filing date of *Invitrogen*'s patents, but that Dr. Goff had not realized that the mutant reverse transcriptase lacked RNase H activity until after that critical date. The court held that it was not until Goff recognized that the mutant lacked RNase H activity that the "invention" in question was conceived by Goff.

The Wold declarations present a similar fact pattern. Appellant relies in part on the development of the KD1 vector as evidence of prior invention. Wold I, ¶ 6, shows that KD1 was made prior to the effective filing date of the Henderson and Little patents. However, it was not until several months after the effective filing date of the Henderson and Little patents, that it was known or appreciated that KD1 overexpressed ADP (Wold I, ¶¶ 7 & 8), and later still that KD1 had been considered as potentially being useful for treating cancer (Wold II, ¶¶ 4 & 5).

Consequently as per the ruling in *Invitrogen*, it was not until after the effective filing date of the Henderson and Little patents that a method of treating cancer with KD1 was conceived by Appellant.

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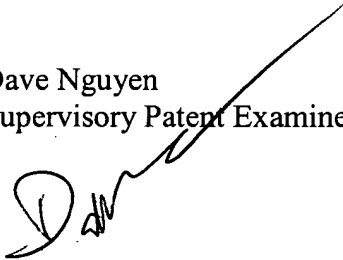
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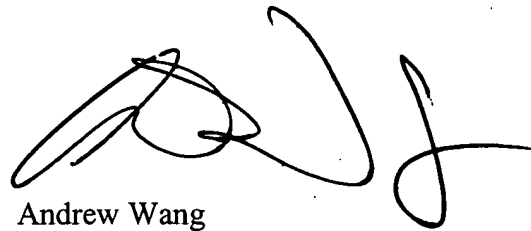
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